



**Natural ASA**  
Strandveien 15  
Pb 165, 1325 Lysaker  
NORWAY  
Phone: +47 67 11 45 00  
Fax: +47 67 11 45 01  
Org. No.: 950 293 225

**Natural ASA**  
Industriveien 42  
N-6160 Hovdebygda  
NORWAY  
Phone: +47 70 04 91 00  
Fax: +47 70 04 91 01

September 1, 2005

Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD,  
20740

AB/FOA

Dear Sir or Madam:

**Re: Premarket Notification for a New Dietary Ingredient**

In accordance with 21 CFR, Part 190, Sec. 190.6 "Requirement for premarket notification," we are submitting this new dietary ingredient notification for the dietary ingredient Omega-3 Phospholipids. Please note the following:

1. Name and Address of the Manufacturer of the New Dietary Ingredient

Natural ASA  
Industriveien 42  
N – 6160 Hovdebygda  
Norway

2. Name of the New Dietary Ingredient

Omega-3 Phospholipids

3. Description of the Dietary Supplement that will contain the New Dietary Ingredient

Omega-3 Phospholipids is predominantly a mixture of phospholipids and triglycerides, with a small amount of ethyl esters and free fatty acids. Omega-3 Phospholipids is rich in eicosapentaenoic acid, docosahexaenoic acid, and lecithin (predominantly phosphatidylcholine). Omega-3 Phospholipids will be packaged in softgel capsules; in addition, Omega-3 Phospholipids may also be used in other applications such as nutritional bars and liquid formulations.

4. Evidence of Safety

Data supporting that Omega-3 Phospholipids is expected to be reasonably safe under the conditions of indicated use are provided in the attachment.

Aims 2005-5764

September 1, 2005

The original and two copies of the Notification are attached, including appendices and references. We trust that the information provided meets the requirements of a New Dietary Ingredient Notification as indicated in 21 CFR §190.6. If you have any questions or comments regarding the content of this submission, please do not hesitate to contact Egil Nilsen at +47 91 18 66 67.

Sincerely,

A handwritten signature in black ink, appearing to read 'Egil Nilsen', written over the printed name.

Egil Nilsen  
Business Development Manager